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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,997	09/23/2002	Barrie Hayes-Gill	469.1094	5818

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,997	HAYES-GILL ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-62* is/are pending in the application.

4a) Of the above claim(s) *48-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-42* is/are rejected.

7)☒ Claim(s) *43-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 48-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/6/06.

Clarification on Claim Term Interpretation

2. Pending claims 25-47 contain various limitations in which a processor is adapted to perform a specified function (i.e., see claims 38-41, 43, 45). It is the policy of the Office to interpret such a limitation to require a processor which is programmed or otherwise configured to perform the specified function. Any previous interpretations of similar claim limitations (i.e., any interpretations explained in Office Action dated 9/12/05) should be disregarded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 35 (and claim 38 depending therefrom) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Examiner cannot find support in the specification for correlating the fetal ECG with a fetal template. Appropriate explanation or correction is required.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 25-27, 31, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative as being unpatentable over, U.S. Patent No. 6,115,624 ("Lewis et al.").

Lewis et al. discloses an apparatus for detecting fetal and/or maternal heart rate, wherein a plurality of ECG electrodes may be located on a lower surface of a pad which is secured to a pregnant women's abdomen (see col. 2, lines 33-65). Fetal and/or maternal ECG activity may be detected with the array of electrodes (see col. 2, lines 50-55), and processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis et al. does not specifically disclose that the

processor utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats of the mother by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that detection of the maternal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate by well known and accepted medical methods.

With respect to claims 26 and 27, Lewis et al. discloses that the array of electrodes includes at least two detectors to detect the heart beats of the fetus, each detector including at least two electrodes (active electrodes 42 and common or reference electrode 41; see col. 4, line 55 - col. 5, line 6).

With respect to claim 31, Lewis et al. discloses that the ECG signal may be utilized by the processor circuitry to derive the fetal and/or maternal heart rate, which may then be displayed on a video display or other monitoring device (see col. 2, lines 58-61). The processed data may be displayed in a useful manner, e.g., on digital display or a chart recorder (see col. 9, lines 1-10).

With respect to claim 42, Examiner considers the apparatus portable.

7. Claims 25-27, 30-31, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative as being unpatentable over, U.S. Patent No. 6,751,498 ("Greenberg et al.").

Greenberg et al. discloses an apparatus for detecting fetal and/or maternal heart rate (see col. 4, lines 1-14). Fetal and/or maternal ECG activity may be detected with the array of electrodes (see col. 2, lines 50-55), and processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis et al. does not specifically disclose that the processor utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats of the mother by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Greenberg et al. such that detection of the maternal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate by well known and accepted medical methods.

With respect to claim 26, Greenberg et al. discloses that the array of electrodes includes at least two detectors to detect the heart beats of the fetus, each detector

including at least two electrodes (for example, electrode strip sensors 34 and 36 each contain a plurality of electrodes; see col. 9, line 50 - col. 10, line 15).

With respect to claims 28-29, Greenberg et al. discloses that a reference fetal waveform is processed against the other abdominal waveforms in order to form an enhanced fetal signal that is a representation of the fetal ECG (see col. 4, lines 34-42 and col. 7, lines 1-48). Examiner considers this fetal ECG to be a virtual ECG signal that is a weighted sum of the ECG signals detected by the detectors.

With respect to claims 30 and 32, Greenberg et al. discloses signal processing for amplifying and filtering the ECG signals.

With respect to claim 31, Greenberg et al. discloses that the ECG signals may be displayed (see col. 7, lines 49-64).

With respect to claim 40, Greenberg et al. discloses suppression of the maternal ECG in order to detect the fetal ECG (see, for example, col. 4, lines 34-52).

With respect to claim 42, Examiner considers the apparatus portable.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,115,624 ("Lewis et al.").

With respect to claims 32, and 36-37, bandpass filters are well known to filter noise components from a detected ECG. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that bandpass filters are utilized in the signal processing of the ECG in order to reduce noise and obtain a more accurate ECG signal.

With respect to claims 33 and 35, Lewis et al. teaches that the processor circuitry may compare the detected signals to a database stored in the memory circuitry to further facilitate the heart rate information in the signals. For example, the database may include information such as standard maternal and/or fetal heart signals which may be compared to the detected signals in order to more accurately derive the desired actual heart rate (see col. 10, lines 43-51).

With respect to claims 34 and a portion of claim 40, subtracting a maternal component from a composite ECG is well known in order to obtain the fetal ECG only (e.g., see U.S. Patent No. 4,781,200 to Baker at col. 8, lines 20-40 or col. 10, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. to utilize the standard maternal heart signal stored in the above-described database in order to obtain the fetal ECG only and monitor the well-being of the fetus.

With respect to claims 38-39 and a portion of claim 40, Lewis et al. discloses that the processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis et al. does not specifically disclose that the processor utilizes ECG peaks in order to determine the fetal heart rate. However,

detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that detection of the fetal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the fetal heart rate by well known and accepted medical methods.

With respect to claim 41, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates.

10. Claims 25-27, 30-32, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,781,200 ("Baker").

Baker discloses an apparatus for detecting the heart rate of a fetus (fetal monitoring system 20), including at least two electrodes positioned on the abdomen of the mother in use for detecting ECG signals (plurality of fetal monitoring sensors 35 may be ECG sensors; see col. 5, lines 1-5), a processor for receiving the signals received from each detector and determining the heart rate of the fetus (control unit 40; see col. 7, lines 20-35). Baker does not specifically disclose that control unit 40 may also determine the heart rate of the mother. However, it is well known in the art to monitor

the maternal heart rate in addition to monitoring the fetal heart rate (i.e., see U.S. Patent No. 5,666,959 which teaches a method and apparatus for deriving a fetal heart rate and a maternal heart rate). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Baker such that it also monitors the maternal heart rate (utilizing the detected maternal ECG) in order to monitor the well being of the mother during pregnancy and labor.

With respect to claim 27, Baker fails to specifically disclose that a common electrode forms one of the electrodes of each detector. It is known in the art to utilize a common reference electrode (see "Lead systems for the abdominal fetal electrocardiogram," which teaches multiple lead configurations for detecting a fetal ECG. The article describes one proposed configuration in which an array of electrodes in placed over the abdomen, unipolar signals are recorded with the common reference being at the lower abdomen (see page 24, fifth full paragraph)). It would have been obvious to one having ordinary skill at the time of applicant's invention to form a common electrode for the multiple sensors of Baker in order to reduce the number of required electrodes.

With respect to claims 30 and 32, Baker discloses a signal processor for amplifying and filtering the ECG signals detected by the detectors (see Figures 6A-6C and associated text).

With respect to claim 31, the control unit 40 of Baker includes a visual display (73) of fetal heart rate and can further display other information such as patient history (see col. 6, lines 57-65). Baker fails to specifically disclose that ECG signals or traces

can be displayed on display 73. Displaying dynamic ECG traces is well known in the art. It would have been obvious to one having ordinary skill at the time of applicant's invention to modify the system of Baker to include such a display in order to provide an operator with the morphology of the ECG trace that may be utilized to detect further abnormalities.

With respect to claim 40, Baker determines the heart rate of the fetus by suppressing the maternal signal (see col. 8, lines 20-40 or col. 10, lines 55-65), detecting peaks of the remaining fetal signal (via peak value processor 183), and determining the time interval between adjacent beats (see col. 18, lines 35-55).

With respect to claim 41, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates (i.e., see Baker at col. 7, lines 25-29).

With respect to claim 42, the apparatus is portable (see Figs. 1 and 2).

Allowable Subject Matter

11. Claims 43-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: claims 43-47 relate to determining the fetal heart rate by distinguishing between "erroneous time intervals" and time intervals having a standard deviation lower than a

predetermined value. Examiner considers the closest prior art of record to be U.S. Patent No. 6,751,498 ("Greenberg et al."). Greenberg et al. teaches an apparatus for detecting the heart rate of a fetus surface electrodes (10) placed on the mother's abdomen and/or lower back to obtain a "combined waveform" of maternal-plus-fetal waveforms. Greenberg et al. teaches distinguishing between "good" EKG signals and "bad" ECG signals by examining the frequency spectrum of the EKG signal in order to assess the signal integrity of the electrode/sensor. In Greenberg, a signal is considered to be "good" when the spectrum is wide and results in a minimum ration magnitude (see col. 8, lines 38-64). Greenberg et al. is concerned with distinguishing channel integrity rather than distinguishing erroneous time intervals, and thus Examiner considers the subject matter of claims 43-47 to be allowable over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
4/21/06

George Manuel
Primary Examiner